

Remarks

The present response is submitted in reply to the Office action issued on July 22, 2008. Claims 1-29 are pending in this application. Claims 13, 15-18 and 27-29 have been withdrawn while the remaining claims have been rejected. By the present response, claim 1 has been amended to incorporate the subject matter of claim 4 (now canceled) therein. Claim 3 has also been canceled. Claim 5 has been amended to depend from claim 1 rather than canceled claim 4. Claim 15 has been amended to clarify an informal matter. No new matter has been added. Reconsideration is respectfully requested in light of the amendments being made hereby and of the following remarks.

Restriction Requirement

The Examiner acknowledges the Applicants' election with traverse of the restriction requirement in the reply filed on March 7, 2008 and states that the Applicants' argument concerning Groups I and II is persuasive, but that there was no argument concerning a common technical feature between either of Groups I or II and Group III. Therefore, the Examiner states that because the Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse.

The Examiner has further acknowledged the Applicants' election of species of (a) oxygen-containing compound, hydrogen peroxide, (b) antioxidant, tocopherols, (c) layer, mono-layer, (d) polymer, cellulose ether, (e) additive, permeation-enhancing substance and (f) active substance, nicotine and the corresponding claims 1-12 and 19-23. Consequently, the Examiner acknowledges that claims 13-18 and 24-29 are withdrawn

from further consideration as being drawn to non-elected subject matter.

As set forth in the present Office action, claims 13-18 and 24-29 are listed as being withdrawn. However, it is noted that the restriction requirement of the Office action dated December 19, 2007 provides that Group I reads on claims 1-12, 14 and 19-26. Moreover, the Applicants elected the claims of Group I by the response filed on March 7, 2008. Therefore, it is believed that claims 13, 15-18 and 27-29 should be listed as withdrawn rather than claims 13-18 and 24-29.

As noted above, the Examiner confirms that the Applicants' arguments concerning Groups I and II were persuasive. Therefore, it is respectfully submitted that it would in turn be obvious for one skilled in the art that if the products of Groups I and II are based on a single inventive concept, then the same would hold true for the process of Group III for the manufacture of said products. Therefore, withdrawal of the restriction requirement is appropriate.

Objection of claim 3 under 35 U.S.C. 112, first paragraph

The Examiner has objected to claim 3 as failing to comply with the written description requirement. Claim 3 has been canceled. Therefore, withdrawal of this objection is appropriate.

Objection of claims 1-12, 14 and 19-26 under 35 U.S.C. 112, second paragraph

The Examiner has objected to claim 3 as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. Claim 3 has been canceled. Therefore, withdrawal of this objection in relation to claim 3 is respectfully requested.

The Examiner has objected to claims 1-12, 14 and 19-26 as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. In particular, the Examiner states that the term "film-like" in claim 1 is a relative term which renders the claim indefinite since the term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree and since one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The Applicants respectfully disagree that the term "film like" in claim 1 is indefinite. "Film like" preparations, also referred to as wafers, are established administration forms in the pharmaceutical industry and are well known to one skilled in the art. In other words, "film like" preparations would clearly be differentiable to one skilled in the art from alternative administration forms, such as tablets, capsules, suppositories, powders, creams, solutions and the like. Therefore, the term "film like" should not be considered indefinite and withdrawal of this objection is requested.

Rejection of claims 1-3 under 35 U.S.C. 102(b)

Claims 1-3 have been rejected under 35 U.S.C. 102(b) as being anticipated by GB 1,061,557 (Deadman). The Examiner states that Deadman teaches a coated or impregnated film (column 1, lines 9-10) and that the invention consists of self-supporting films of gelatin or rice paper coated or impregnated with a drug for oral administration (column 1, lines 29-34). The Examiner further states that the prior art anticipates the presently claimed invention insofar as it discloses a film impregnated with an active substance for oral administration, i.e., in the oral cavity and that since the film is

comprised of natural ingredients, it does not contain any free oxygen or peroxides and will inherently have a peroxide number lower than 15.

The Applicants respectfully disagree with the Examiner's conclusion and submit that the present invention is patentably distinct from the invention disclosed in the Deadman reference. Moreover, the Applicants submit that each and every feature set forth in the present claims is not taught or disclosed by the cited reference, and therefore the reference does not anticipate the present invention as set forth in the present claims.

The Applicants submit that Deadman clearly fails to teach or describe the newly incorporated limitation of presently amended claim 1, i.e., wherein said preparation contains at least one antioxidant.

Still further, it is submitted that peroxides are common compounds in natural products. For example, medically relevant peroxide containing compounds are isolated from chamomile and other plants. This corresponds with the findings of the cited reference for Müller (discussed further below), in which the POZ (peroxide number) of various compounds, including natural products such as pinene, oleyalcohol or limonene, was determined. These POZ clearly demonstrated that natural products also contain peroxides in significant amounts.

Moreover, catalase is a common enzyme found in nearly all living organisms whose function includes catalyzing the decomposition of hydrogen peroxide to water and oxygen. As catalase is found in living organisms, it is obvious that the substrate for this enzyme, a peroxide, is found in those organisms and therefore also in natural products

derived therefrom. Furthermore, many chemical compounds found in living organisms contain ethers as functional groups, e.g., sugars as found in cellulose. As it is well known in the art, ethers are easily susceptible to peroxidation forming ether peroxides when exposed to oxygen or hydroperoxide. Consequently, with hydroperoxides as well as ether compounds present in living organisms, it is evident that many natural products derived from said organisms contain in various degrees peroxide compounds rather than being per se free of peroxides.

Therefore, the reference of Deadman simply does not anticipate the presently claimed invention. Withdrawal of the present rejection is respectfully requested.

Rejection of claims 1-12 and 19-23 under 35 U.S.C. 103(a)

Claims 1-12 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over WIPO 01/080837, U.S. Publication No. 2003/0049308 (Theobald, et al.) in view of WIPO 01/39753, U.S. Patent No. 6,699,498 (Müller). According to the Examiner, Theobald, et al. teach a transdermal or transmucosal administration form comprising nicotine, as well as the remaining limitations of the aforementioned claims. However, the Examiner states that Theobald, et al. fail to teach the limitation of “peroxide number” or that the invention is further comprised of antioxidants.

The Examiner refers to Müller which, the Examiner states, teaches a transdermal therapeutic system (TTS) in which the formation of oxidative degradation products of the oxidation sensitive active substance present is reduced during storage, and that this objective is achieved by using only those formulations constituents which are

substantially free of hydroperoxides (column 6, lines 7-15). The Examiner additionally provides in the Office action that Müller essentially makes up for any other deficiencies of Theobald, et al., except Müller fails to teach a film-like preparation comprised of nicotine. In this regard, the Examiner states that it is generally *prima facie* obvious to select a compound based on its suitability for its intended use. Therefore, the Examiner concludes that it would have been obvious to modify the invention of Theobald, et al. to use the tocopherol of Müller motivated by the desire to improve the stability as taught by Müller. The Examiner states that it would have also been obvious to modify the constituents of the invention of Theobald, et al. by reducing them with the sodium hydrogen sulfite of Müller prior to use, motivated by the desire to lower the peroxide number to 5 by removing peroxides, which improves the stability as taught by Müller.

The Applicants respectfully submit that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all of the claim limitation. The Applicants respectfully submit that one skilled in the art would have no suggestion or motivation to combine the aforementioned references in order to arrive at the present invention. Additionally, even if one skilled in the art were to consider the combination of teachings of the prior art, each and every limitation of the present invention would not be disclosed, nor would there be a reasonable expectation of success if the aforementioned references were to be considered.

The Applicants submit that the presently claimed invention is directed to a film-like, active substance-containing preparation for application in the oral cavity or for transmucosal application, wherein the preparation has a maximum peroxide number of 40 and the preparation contains at least one antioxidant selected from the group consisting of sodium sulfite, sodium disulfite, sodium metabisulfite, thioglycerol, thioglycol acid, propyl gallate, octyl gallate, butylhydroxyanisol and butylhydroxytoluene.

Theobald, et al. teach a transmucosal pharmaceutical administration form for the treatment of nicotine dependency. In one embodiment, the administration form comprises at least one pharmaceutical active substance in a film like carrier which can be based on starch, carboxymethylcellulose or polyacrylic acid. The matrix containing the active substance may further comprise additives which promote skin permeation of the active substance.

However, preparations according to the present invention having a maximum peroxide number and containing antioxidants are not taught or disclosed at all by Theobald, et al. It is clear that Theobald, et al. fail to teach each and every limitation of present claim 1, as amended herein.

Müller teaches transdermal therapeutic systems comprising at least one layer which have a peroxide number (PON) not greater than 20 with regard to each formulation constituent. Furthermore, the use of tocopherols and its derivatives, as well as ascorbyl palmitate, as antioxidants to reduce the oxidative stress in the composition are mentioned. However, a film-like preparation for oral application or transmucosal application according to the present invention, which naturally has a totally different composition due

to a different task and application, is not taught or described at all by Müller. Moreover, the use of antioxidants according to claim 1 of the present invention, such as thioglycerol, thioglycol acid, propyl gallate, octyl gallate, butylhydroxyanisol and butylhydroxytoluene, and especially antioxidants selected from the group of inorganic compounds such as sodium sulfite, sodium disulfite and sodium metabisulfite to further enhance the stability of the active substance and to prolong the shelf-life of the preparation are not taught or disclosed at all by Müller.

In conclusion, it is submitted that the preparations according to claim 1 of the present invention comprising the recited antioxidants is not taught or suggested by Theobald, et al., alone or in combination with Müller, and there would therefore be no motivation for one skilled in the art to combine said teachings to arrive at the presently claimed invention. Moreover, even if such combination were to be done, each and every limitation of the presently claimed invention would not be taught or disclosed. Withdrawal of this rejection is strongly requested.


Conclusion

In light of the foregoing claims and arguments, it is believed that the present application is in condition for allowance, and such action is earnestly solicited. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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